



7-19-04

JFW

EXPRESS MAIL NO. EV335394329US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Edward A. Neuwelt et al.
Application No. : 10/698,955
Filed : October 31, 2003
For : USE OF THIOL-BASED COMPOSITIONS IN TREATING
CHEMOTHERAPEUTIC AGENT-INDUCED
THROMBOCYTOPENIA

Art Unit : 1616
Docket No. : 720109.404
Date : July 15, 2004

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents:


In accordance with 37 CFR 1.56 and 1.97 through 1.98, applicants wish to make known to the U.S. Patent and Trademark Office the references set forth on the attached Form PTO-1449 (copies of the cited references are enclosed). As to any reference supplied, applicants do not admit that it is "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserve the right to traverse or antedate any such reference, as by a showing under 37 CFR 1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with applicants' duty to disclose all information they are aware of which is believed relevant to the examination of the above-identified application, applicants believe that their invention is patentable.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Applicants believe this Information Disclosure Statement has been timely filed, however, the Director is authorized to charge any fee due by way of this Information Disclosure Statement to our Deposit Account No. 19-1090.

Respectfully submitted,

Seed Intellectual Property Law Group PLLC



Qing Lin, Ph.D.

Registration No. 53,937

QXL:ljt

Enclosures:

- Postcard
- Transmittal Form
- Form PTO-1449 (4 Sheets)
- Cited References (42)

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

\498637



EXPRESS MAIL NO. EV335394329US

**TRANSMITTAL
FORM***(To be used for all correspondence
after initial filing)*

Application Number	10/698,955
Filing Date	October 31, 2003
First Named Inventor	Edward A. Neuwelt
Art Unit	1616
Examiner Name	
Attorney Docket No.	720109.404

ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Response <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement; Form PTO-1449 (4 Sheets) <input checked="" type="checkbox"/> 42 Cited References <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts under 37 C.F.R. 1.52 or 1.53 <input type="checkbox"/> Response to Missing Parts/Incomplete Application	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Request for Corrected Filing Receipt <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation, Change of Correspondence Address <input type="checkbox"/> Declaration <input type="checkbox"/> Statement under 37 CFR 3.73(b) <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund	<input type="checkbox"/> CD(s), Number of CD(s) _____ <input type="checkbox"/> After Allowance Communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (<i>Appeal Notice, Brief, Reply Brief</i>) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Return Receipt Postcard <input type="checkbox"/> Additional Enclosure(s) (<i>please identify below</i>): _____ _____ _____
---	---	--

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Individual Name	Qing Lin, Ph.D. Reg. No. 53,937	Customer Number 00500
Signature		
Date	July 15, 2004	

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name		
Signature		Date:

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
1498633

FORM PTO 1449
(REV. 7-80)

JUL 15 2004

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
720109.404APPLICATION NO.
10/698,955

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

APPLICANTS

Edward S. Neuwelt et al.

FILING DATE

October 31, 2003

GROUP ART UNIT

1616

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,906,984	05/25/99	Capizzi et al.	514	114	
	AB	5,994,409	11/30/99	Stogniew et al.	514	665	
	AC	6,573,253	06/03/03	Stogniew	514	114	
	AD	2003/0157191	08/21/03	Kil et al.	424	649	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AE	EP 624377 B1	01/23/02	EPO		
	AF	WO 92/08448	05/29/92	WIPO		
	AG	WO 94/00141	01/06/94	WIPO		
	AH	WO 94/03179	02/17/94	WIPO		
	AI	WO 96/14852	05/23/96	WIPO		
	AJ	WO 96/26643	09/06/96	WIPO		
	AK	WO 98/11898	03/26/98	WIPO		
	AL	WO 98/34622	08/13/98	WIPO		
	AM	WO 99/29312	06/17/99	WIPO		
	AN	WO 01/80832	11/01/01	WIPO		
	AO	WO 02/17962	03/07/02	WIPO		

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AP	Alvarado, C.S. et al., "Chemotherapy for Patients with Recurrent or Refractory Neuroblastoma: A POG Phase II Study," <i>Journal of Pediatric Hematology/Oncology</i> 19(1): 62-67, February 1997.
	AQ	Blakley, B.W. et al., "Strategies for Prevention of Toxicity Caused by Platinum-Based Chemotherapy: Review and Summary of the Annual Meeting of the Blood-Brain Barrier Disruption Program, Gleneden Beach, Oregon, March 10, 2001," <i>The Laryngoscope</i> 112(11): 1997-2001, November 2002.

EXAMINER

DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

FORM PTO-1449
(REV.7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

720109.404

APPLICATION NO.

10/698,955

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

APPLICANTS

Edward S. Neuwelt et al.

FILING DATE

October 31, 2003

GROUP ART UNIT

1616

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BA						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	BB					

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	BC	Blay, J.Y. et al., "A Risk Model for Thrombocytopenia Requiring Platelet Transfusion After Cytotoxic Chemotherapy," <i>Blood</i> 92(2): 405-410, July 15, 1998.
	BD	Budd, G.T. et al., "Clinical Effects of Amifostine (Ethyol®) in Patients Treated with Carboplatin," <i>European Journal of Cancer</i> 32A(Suppl. 4): S43-S45, October 1996.
	BE	Butterworth, M. et al., "Cysteine Isopropylester Protects Against Paracetamol-Induced Toxicity," <i>Biochemical Pharmacology</i> 43(3): 483-488, 1992.
	BF	Case, B.C. et al., "The Pharmacokinetics and Pharmacodynamics of GW395058, a Peptide Agonist of the Thrombopoietin Receptor, in the Dog, a Large-Animal Model of Chemotherapy-Induced Thrombocytopenia," <i>Stem Cells</i> 18: 360-365, 2000.
	BG	Dahlborg, S.A. et al., "The Potential for Complete and Durable Response in Nonglial Primary Brain Tumors in Children and Young Adults with Enhanced Chemotherapy Delivery," <i>The Cancer Journal from Scientific American</i> 4(2): 110-124, March/April 1998.
	BH	Database BIOSIS, STN/CAS Online, Accession No. 2002:129589, Doolittle et al., <i>Blood</i> 98(11, Part 1): 37a-38a, November 2001.
	BI	de Jong, R.S. et al., "Phase II Study of Intraperitoneal Cisplatin Plus Systemic Etoposide as Second-line Treatment in Patients With Small Volume Residual Ovarian Cancer," <i>European Journal of Cancer</i> 31A(5): 709-713, 1995.
	BJ	Doolittle, N.D. et al., "Delayed Sodium Thiosulfate as an Otoprotectant Against Carboplatin-induced Hearing Loss in Patients with Malignant Brain Tumors," <i>Clinical Cancer Research</i> 7: 493-500, March 2001.
	BK	Einhorn and Loehrer, "Ifosfamide chemotherapy for pancreatic carcinoma," <i>Cancer Chemotherapy and Pharmacology</i> 18(Suppl. 2): S51-S54, 1986.
	BL	Harker, L.A. et al., "Prevention of Thrombocytopenia and Neutropenia in a Nonhuman Primate Model of Marrow Suppressive Chemotherapy by Combining Pegylated Recombinant Human Megakaryocyte Growth and Development Factor and Recombinant Human Granulocyte Colony-Stimulating Factor," <i>Blood</i> 89(1): 155-165, January 1, 1997.

EXAMINER

DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

FORM PTO-1449
(REV.7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.

720109.404

APPLICATION NO.

10/698,955

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

APPLICANTS

Edward S. Neuwelt et al.

FILING DATE

October 31, 2003

GROUP ART UNIT

1616

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	CA						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	CB					

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	CC	Howell, S.B. et al., "Intraperitoneal Cisplatin with Systemic Thiosulfate Protection," <i>Annals of Internal Medicine</i> 97(6): 845-851, December 1982.
	CD	Isaacs, C. et al., "Randomized Placebo-Controlled Study of Recombinant Human Interleukin-11 to Prevent Chemotherapy-Induced Thrombocytopenia in Patients With Breast Cancer Receiving Dose-Intensive Cyclophosphamide and Doxorubicin," <i>Journal of Clinical Oncology</i> 15(11): 3368-3377, November 1997.
	CE	Iwamoto, Y. et al., "Two-Route Chemotherapy Using High-Dose Ip Cisplatin and Iv Sodium Thiosulfate, Its Antidote, for Peritoneally Disseminated Cancer in Mice," <i>Cancer Treatment Reports</i> 68(11): 1367-1373, November 1984.
	CF	Kim, S. et al., "Dose intensification of cisplatin chemotherapy through biweekly administration," <i>Annals of Oncology</i> 4: 221-227, 1993.
	CG	Muldoon, L.L. et al., "Delayed Administration of Sodium Thiosulfate in Animal Models Reduces Platinum Ototoxicity without Reduction of Antitumor Activity," <i>Clinical Cancer Research</i> 6: 309-315, January 2000.
	CH	Muldoon, L.L. et al., "Rescue from Enhanced Alkylator-Induced Cell Death with Low Molecular Weight Sulfur-Containing Chemoprotectants," <i>The Journal of Pharmacology and Experimental Therapeutics</i> 296(3): 797-805, 2001.
	CI	Neuwelt, E.A. et al., "First Evidence of Otoprotection Against Carboplatin-Induced Hearing Loss with a Two-Compartment System in Patients with Central Nervous System Malignancy Using Sodium Thiosulfate," <i>The Journal of Pharmacology and Experimental Therapeutics</i> 286(1): 77-84, 1998.
	CJ	Neuwelt, E.A. et al., "In Vitro and Animal Studies of Sodium Thiosulfate as a Potential Chemoprotectant against Carboplatin-induced Ototoxicity," <i>Cancer Research</i> 56(4): 706-709, February 15, 1996.
	CK	Neuwelt, E.A. et al., "Therapeutic Efficacy of Aortic Administration of N-Acetylcysteine as a Chemoprotectant against Bone Marrow Toxicity after Intracarotid Administration of Alkylators, with or without Glutathione Depletion in a Rat Model," <i>Cancer Research</i> 61: 7868-7874, November 1, 2001.

EXAMINER

DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 720109.404		APPLICATION NO. 10/698,955	
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				APPLICANTS Edward S. Neuwelt et al.			
				FILING DATE October 31, 2003		GROUP ART UNIT 1616	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	DA						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY		TRANSLATION	
						YES	NO
	DB						
OTHER PRIOR ART <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	DC	Piperno, E. et al., "Pathophysiology of Acetaminophen Overdosage Toxicity: Implication for Management," <i>Pediatrics</i> 62(5 - Supplement): 880-889, November 1978.					
	DD	Robbins, K.T. et al., "Efficacy of Targeted Supradose Cisplatin and Concomitant Radiation Therapy for Advanced Head and Neck Cancer: The Memphis Experience," <i>International Journal of Radiation Oncology Biology Physics</i> 38(2): 263-271, May 1, 1997.					
	DE	Trail, P.A. et al., "Enhanced Antitumor Activity of Paclitaxel in Combination with the Anticarcinoma Immunoconjugate BR96-Doxorubicin," <i>Clinical Cancer Research</i> 5: 3632-3638, November 1999.					
	DF	Vermeulen, N.P.E. et al., "Toxicity of fotemustine in rat hepatocytes and mechanism-based protection against it," <i>Chemico-Biological Interactions</i> 110: 139-158, 1998.					
	DG	Verschraagen, M. et al., "Pharmacokinetics and preliminary clinical data of the novel chemoprotectant BNP7787 and cisplatin and their metabolites," <i>Clinical Pharmacology & Therapeutics</i> 74(2): 157-169, August 2003.					
	DH	Wheeler, B.M. et al., "Ifosfamide in Refractory Male Germ Cell Tumors," <i>Journal of Clinical Oncology</i> 4(1): 28-34, January 1986.					
	DI						
	DJ						
	DK						
	DL						
EXAMINER				DATE CONSIDERED			
* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance <u>and</u> not considered. Include copy of this form with next communication to applicant(s).							